KELLEY DRYE & WARREN LLP
David Fink (STATE BAR NO. 169212)
10100 Santa Monica Boulevard, Twenty-Third Floor
Los Angeles, California 90067-4008
Telephone: (310) 712-6100
Facsimile: (310) 712-6199
dfink@kelleydrye.com
Attorneys for Amicus Curiae
The Council for Responsible Nutrition

UNITED STATES DISTRICT COURT

SOUTHERN DISTRICT OF CALIFORNIA

TATIANA KOROLSHTEYN, on behalf of herself and all others similarly situated

Plaintiffs,

v.

COSTCO WHOLESALE CORPORATION, and NBTY, INC.

Defendants.

CASE NO.: 3:15-CV-00709-CAB-RBB

NOTICE OF MOTION FOR PERMISSION TO FILE A BRIEF AMICUS CURIAE

Date: June 19, 2017
Time: 10:00 a.m.
Judge: Hon. Cathy Ann Beneivengo
Courtroom: 4C

[Memorandum of Point and Authorities and *Proposed Amicus Curiae* brief filed concurrently herewith]

PER CHAMBERS RULES, NO ORAL ARGUMENT UNLESS SEPARATELY ORDERED BY THE COURT

TO ALL PARTIES AND THEIR ATTORNEYS OF RECORD:

PLEASE TAKE NOTICE that on June 19, 2017, at 10:00 a.m., in Courtroom 4C of the above-entitled court, located at 221 West Broadway, San Diego, California, The Council for Responsible Nutrition, will, and hereby do, move for permission of file the accompanying Brief Amicus Curiae (attached hereto as Exhibit A).

This motion is based on this Notice, the Memorandum of Points and Authorities filed herewith, and the Brief Amicus Curiae.

DATED: May 15, 2017

KELLEY DRYE & WARREN LLP

By: */s/ David E. Fink*
David E. Fink

10100 Santa Monica Blvd., 23rd Floor
Los Angeles, California 90067
Telephone: (310) 712-6100
Facsimile: (310) 712-6199
dfink@kelleydrye.com
Attorneys for Amicus Curiae
The Council for Responsible Nutrition

CERTIFICATE OF SERVICE

I hereby certify that I electronically filed the foregoing with the Clerk of the Court using the CM/ECF system which will send notification of such filing to the Electronic Service List for this Case.

Dated: May 15, 2017

KELLEY DRYE & WARREN LLP

By: */s/ David E. Fink*
David E. Fink
Attorneys for Amicus Curiae
The Council for Responsible Nutrition

EXHIBIT A

EXHIBIT A

KELLEY DRYE & WARREN LLP
David Fink (STATE BAR NO. 169212)
10100 Santa Monica Boulevard, Twenty-Third Floor
Los Angeles, California 90067-4008
Telephone: (310) 712-6100
Facsimile: (310) 712-6199
dfink@kelleydrye.com
Attorneys for Amicus Curiae
The Council for Responsible Nutrition

UNITED STATES DISTRICT COURT

SOUTHERN DISTRICT OF CALIFORNIA

TATIANA KOROLSHTEYN, on behalf of herself and all others similarly situated

Plaintiffs,

v.

COSTCO WHOLESALE CORPORATION, and NBTY, INC.

Defendants.

CASE NO.: 3:15-CV-00709-CAB-RBB

BRIEF OF AMICUS CURIAE THE COUNCIL FOR RESPONSIBLE NUTRITION

Date: June 19, 2017
Time:10:00 a.m.
Judge: Hon. Cathy Ann Bencivengo
Courtroom: 4C

PER CHAMBERS RULES, NO ORAL ARGUMENT UNLESS SEPARATELY ORDERED BY THE COURT

TABLE OF CONTENTS

Page

TABLE OF AUTHORITIES

Page(s)

Cases

Statutes

Other Authorities

INTEREST OF THE COUNCIL FOR RESPONSIBLE NUTRITION

The Council for Responsible Nutrition ("CRN") is the leading trade association for the dietary supplement industry. CRN represents more than 150 companies worldwide that manufacture dietary ingredients or dietary supplements, or supply services to those manufacturers. CRN members market popular national brands, as well as the store brands sold by major supermarket, drug store, and discount chains. CRN members also include mainstream direct selling companies and companies marketing products through natural food stores.

CRN has a special interest in the instant case because what is at issue, in significant part, is the appropriate burden of proof for private litigants bringing false advertising cases. The current, prevailing standard allows only government actors – not private actors – to bring cases based on alleged weaknesses in underlying substantiation. This standard appropriately recognizes that government actors are uniquely positioned to consider complex bodies of scientific literature, and issue uniform pronouncements while weighing the public health benefits. If the current standard is overturned, well-reasoned protections for advertisers – and consumers who buy their products – will be eroded. A departure from this standard would directly and adversely impact not only Defendants, but also the broader dietary supplement industry.

While the Defendants' brief touches on the appropriate legal standard, its primary focus is to demonstrate that the companies cannot be held liable with regard to the particular products at issue. The companies' brief therefore does not fully represent the interests of the broader dietary supplement industry in guarding against a wholesale change in the underlying law. Given CRN's active involvement and engagement with a broad range of dietary supplement companies, CRN believes it offers an important perspective.

Although not a focus of this brief, CRN believes that a private plaintiff action against cognition and brain-related claims for gingko products is particularly inappropriate given the underlying body of scientific evidence. Many institutions, such as the World Health Organization and Health Canada, have recognized the brain-related benefits of ginkgo.

INTRODUCTION AND SUMMARY OF ARGUMENT

In the landmark case, *King Bio*, the California Court of Appeal drew a crucial distinction between private litigants and regulators who allege deceptive advertising. Based on the structure and intent of the underlying laws governing deceptive advertising, *King Bio* held that only regulators may premise false advertising cases on a lack of substantiation. Private litigants, however, must identify facts that would affirmatively prove that an advertising claim is false or misleading.

In the fourteen years since *King Bio*, the vast majority of courts have continued to limit the role of private litigants. Courts have scrutinized facts identified by private litigants and allowed cases to proceed only where the facts offered could prove actual falsity or deception. Where plaintiffs have merely shown that the underlying science is weak or equivocal, courts have rejected claims by private litigants.

One recent case, however, misapplied this well-settled standard, where the court allowed a private litigant to proceed with a false advertising based merely on a critique of the advertiser's substantiation. Although two other courts have acknowledged this holding, both ultimately granted motions for summary judgment in favor of defendants. Should this court or other courts follow this single errant case, protections for both advertisers and consumers who buy their products will be eroded.

ARGUMENT

I. THIS COURT SHOULD FOLLOW *KING BIO* AND REQUIRE PRIVATE PLAINTIFFS TO PROVE FALSITY

A. *King Bio* Created a Higher Burden of Proof for Private Litigants in False Advertising Cases

In *King Bio*, a private litigant alleged that a seller of homeopathic remedies had violated California's unlawful competition and false advertising laws by disseminating health benefit claims that lacked a "scientific basis." *Nat'l Council Against Health Fraud, Inc. v. King Bio Pharm., Inc.*, 107 Cal. App. 4th 1336, 1340-1341 (2003). The plaintiff offered no evidence in support of its allegations; rather, the plaintiff argued that "the burden of proof should be shifted to [the defendant] to prove its products' efficacy." *Id.* The court soundly and appropriately rejected this theory.

The court reviewed California's Unfair Competition Law ("UCL") (Bus. & Prof. Code § 17200 et seq.) and False Advertising Law ("FAL") (Bus. & Prof. Code § 17500 et seq.) and determined that the statutes clearly and expressly empower regulators, including the state Attorney General and district attorneys, to demand "evidence of the facts on which such advertising claims are based." *Id.* at 1343 (citing Bus. & Prof. Code § 17508). The court, however, found that private plaintiffs were in no way similarly empowered. *Id.* at 1345 ("Private plaintiffs are not authorized to demand substantiation for advertising claims."). The court further observed that this California statutory scheme "is very similar" to the Federal Trade Commission Act ("FTCA"). *Id.* at 1350 (noting the similarities between Section 17508 and the FTCA).

The court reasoned that because government actors are uniquely empowered to undertake investigations into the weight and reliability of an advertiser's substantiation, only government actors may bring false advertising cases based on a lack of substantiation. *Id.* at 1349. To allow private actors to also base cases on a lack of substantiation would "thwart the intent of the Legislature." *Id.* at 1345. The

court correctly held that private plaintiffs must actually prove that advertising claims are false or misleading, for example, by testing a product themselves. *Id.* at 1348. The court also observed that the distinction, embodied in the law, between private and government actors "prevents undue harassment of advertisers" and allows for "the least burdensome method of obtaining substantiation for advertising claims." *Id.* at 1345.

Most courts have since followed *King Bio* and properly limited the role of private plaintiffs in false advertising cases.

B. The Vast Majority of Courts Have Followed *King Bio* and Required Private Litigants to Identify Facts That Would Affirmatively Prove That Advertising Is False or Misleading

In the fourteen years since *King Bio*, California courts – and courts in many other jurisdictions – have recognized that the case represents well-established law. *Racies v. Quincy Bioscience, LLC*, No. 15-cv-00292-HSG, 2015 WL 2398268, at *3 (N.D. Cal. May 19, 2015) ("[i]t is well-settled that private litigants may not bring any UCL claims based on alleged lack of substantiation"); *Kwan v. SanMedica Int'l*, No. 15-15496, 2017 WL 1416483, at *6 (9th Cir. Apr. 21, 2017) ("[I]t is readily apparent that *King Bio's* holding is firmly established in California law."); *Franulovic v. Coca Cola Co.*, 390 Fed.Appx. 125, at 128 (3rd Cir. 2010) ("[A] New Jersey Consumer Fraud Act claim cannot be premised on a prior substantiation theory of liability.").

Moreover, the vast majority of courts have properly interpreted *King Bio* as requiring private plaintiffs to identify facts that, if proven, would demonstrate that claims are actually false or misleading. *See, e.g., Bronson v. Johnson & Johnson, Inc.*, No. C 12-04184 CRB, 2013 WL 1629191, at *8 (N.D. Cal. Apr. 16, 2013) ("Claims that rest on a lack of substantiation, instead of provable falsehood, are not cognizable under the California consumer protection laws."); *Quinn v. Walgreen Co.*, 958 F.Supp.2d 533, 544 (S.D.N.Y. 2013) (private litigant must present facts that, if true, would show that advertising claims are "affirmatively false"); *Fraker v. Bayer*

Corp., No. CV F 08-1564, 2009 WL 5865687, at *8 (E.D. Cal. Oct. 6, 2009) (granting motion to dismiss where Plaintiff failed to identify any evidence that might show that the "advertising claims with respect to [the product] are actually false"); *Kwan*, No. 15-15496, 2017 WL 1416483, at *6 (granting motion to dismiss where plaintiff failed to identify any "specific facts pointing to actual falsehood").

For example, in *Stanley v. Bayer Healthcare LLC*, the plaintiff challenged advertising claims stating that a probiotic supplement "promote[s] overall digestive health" and "helps defend against" symptoms, such as gas and bloating. No. 11cv862-IEG(BLM), 2012 WL 1132920, at *1-2 (S.D. Cal. Apr. 3, 2012). The plaintiffs alleged that the claims were false and misleading in violation of California law because there were no studies on the specific blend of probiotics in the product, *id.* at *6, and "a majority of data generated in peer reviewed, double blind, placebo controlled studies relating to probiotics, largely suggests that probiotics have little effect on human digestive or immune health." *Id.* at *5.

The court reviewed the plaintiff's expert testimony, but ultimately determined that "none of the Plaintiff's experts opine that the claims [at issue] are actually false." *Id.* at *5. The court observed that "[i]nstead, Plaintiff's experts repeatedly assert the [advertising claims] are rendered false or misleading due to a lack of substantiation." *Id.* The court pointed to statements by one of the plaintiff's experts who testified that the effects of probiotics "var[y] dramatically between individuals" and that the science is "inconclusive" on whether probiotics might work for some people. *Id.* at *5-6. The court dismissed the plaintiff's allegations, as inappropriately premised on a lack of substantiation. *Id.* at *5-9, *11. It stated clearly that "[t]he burden is upon Plaintiff to present evidence that Defendant's advertising claims are *actually false or misleading*." *Id.* at *9 (emphasis added).

In *Scheuerman v. Nestle Healthcare Nutrition, Inc.*, plaintiffs challenged advertising claims for Boost Kids Essentials, a nutritional beverage for children. No. 10-3684 (FSH)(PS), 2012 WL 2916827, at *1 (D.N.J. July 17, 2012). The advertising

claims at issue indicated that Boost Kids Essentials was "clinically shown" to help strengthen the immune system. *Id.* at *1. Relying on expert testimony, the plaintiffs sought to show that the "clinically shown" claims "were deceptive and misleading because they were made without any reasonable basis for doing so and without substantiating them." *Id.* (internal quotation omitted). The court, however, found that this legal theory failed given that the plaintiff's "experts . . . d[id] not demonstrate that there is *no scientific support* for Nestle's 'clinically shown' advertising claims." *Id.* at *8 (emphasis added). The court further explained, "Plaintiffs' experts and its other facts all boil down to a claim that Nestle's scientific support . . . is not as strong as it should be and do[es] not substantiate [the] claims." *Id.* at *7. The court granted summary judgement in favor of the defendants, again finding that "[i]t is the Plaintiff's burden to *affirmatively prove* that [an advertising claim] is a false or misleading statement and not merely one that is unsubstantiated." *Id.* (emphasis added).

In *Racies v. Quincy Bioscience, LLC*, the plaintiff challenged claims for a brain health dietary supplement sold by the defendant, including "Clinically Tested Ingredient," "improves memory," and "Healthy Brain Function." *See* No. 15-cv-00292-HSG, 2015 WL 2398268, at *1. The plaintiff based its allegations on two separate rationales. First, it alleged that it was unable to find any public record of a clinical study on the product and that studies summarized on the defendant's product website were not "competent and reliable scientific evidence." *Id.* at *1-2. Second, the plaintiff alleged that the advertising claims could not possibly be supported given that an "expert[] in brain chemistry" concluded that the active ingredient in the product is digested into "common amino acids no different from other common food products" and any amino acids derived from the product would be "massively diluted" by other amino acids and therefore "could have no measurable effect on the brain." *Id.* at *1 (internal citation omitted).

In dismissing the lack of substantiation allegations, the court restated the findings from *King Bio* that the California legislature "has expressly permitted prosecuting authorities, but not private plaintiffs, to require substantiation." *Id.* at *3 (citing *King Bio*, 107 Cal. App. 4th at 1345).

The court allowed what it called the "brain chemistry claims" to proceed. *Id.* at *4. The court reasoned that "[i]f Plaintiff successfully proves that the [active ingredient] in the Product is destroyed by the human digestive system or is of such a trivial amount that it cannot biologically affect memory or support brain function, he will be able to affirmatively prove the falsity of Defendant's Product claims." *Id.* It is clear that the court correctly applied the *King Bio* standard by dismissing the plaintiff's lack of substantiation claims and permitting only claims based on alleged falsity to proceed.

Finally, in *In re GNC*, the Fourth Circuit reached a similar holding that acknowledged the need to identify facts that, if true, would affirmatively disprove claims. 789 F.3d 505, 515-516 (4th Cir. 2015). In this case, plaintiffs' challenged advertising claims for joint supplements that contained glucosamine and chondroitin, among other ingredients, such as hyaluronic acid and willow bark extract. *Id.* at 509-510. The advertising at issue included claims such as "promote[] joint health and mobility" and "protect[] from wear and tear of exercise." *Id.* at 509. Plaintiffs alleged that "the vast weight of competent and reliable scientific evidence" proved that the claims were false. *Id.* at 510 (internal citation omitted). The plaintiffs noted multiple peer-reviewed and published studies on glucosamine and chondroitin and two studies on one other ingredient. *Id.* at 510-511. The Fourth Circuit found that the plaintiff's allegations lacked merit and granted the defendant's motion for summary judgment.

The court reasoned that the plaintiffs' own arguments revealed that the evidence on glucosamine and chondroitin "is equivocal." *Id.* at 515. Equivocal science cannot affirmatively prove that an advertising claim false. The court noted that "[w]hen litigants concede that some reasonable and duly qualified scientific

experts agree with a scientific proposition, they cannot also argue that the proposition is literally false." *Id.* at 515 (internal quotation omitted). In order to state an actionable claim, the court held that the plaintiff must have alleged "that *all* reasonable experts in the field agree that the representations are false" and that "*all* of the ingredients contained in the products are incapable of providing the represented benefits." *Id.* at 516 (emphasis added).

Each of the foregoing decisions aptly recognizes that private plaintiffs seeking to challenge a company's advertising must identify facts that could affirmatively demonstrate that advertising claims are actually false or misleading.[1] With this requirement in place, plaintiffs cannot usurp the role of government actors and argue weaknesses in the substantiation. This court should follow these courts in correctly interpreting and applying *King Bio*.

II. THIS COURT SHOULD NOT FOLLOW A RECENT CASE THAT MISAPPLIES THE STANDARD SET FORTH IN *KING BIO*

In *Mullins v. Premier Nutrition Corp.*, 178 F.Supp.3d 867 (N.D. Cal. Apr. 15, 2016), the Northern District of California incorrectly departed from the sound legal standard set forth in *King Bio*. The plaintiffs in *Mullins* challenged advertising claims for Joint Juice, a liquid dietary supplement containing glucosamine and chondroitin. 178 F.Supp.3d at 875. The defendant offered expert evidence in support of its advertising claims and pointed to studies showing the beneficial effects of glucosamine and chondroitin. *Id.* at 884-886. In response, the plaintiff offered expert evidence and clinical studies that allegedly disproved the defendant's advertising claims. *Id.* at 882-886.

The court accepted the plaintiff's evidence and arguments as sufficient to survive a motion for summary judgment by the defendants, holding that the plaintiff

[1] CRN does not necessarily agree with the factual analyses or outcomes in the identified cases. Each case, however, correctly interprets *King Bio* to require plaintiffs to identify facts that would affirmatively show advertising to be false or misleading.

could properly show that the Joint Juice claims were misleading if she could show that "the vast weight of competent evidence establishes that the [defendant's] health claims [were] false." *Id.* at 895. The court further explained that the plaintiff had made a threshold showing by offering "principled critiques" of the studies relied upon by the defendant and its expert. *Id.* at 895-896.

This holding is incorrect because, as indicated in the cases properly interpreting *King Bio*, an advertising claim cannot be *actually or affirmatively* misleading if it is open to any debate or differing expert opinions. If advertising claims are debatable at all, they are necessarily only potentially false or misleading and therefore insufficient.

Although two courts have acknowledged the erroneous holding in *Mullins*, both courts ultimately granted summary judgement in favor of defendants. *See Sonner v. Schwabe N. Am., Inc*., No. EDCV 15-1358-VAP (SPx), 2017 WL 474106, at *5, *7 (C.D. Cal. Feb. 2, 2017) (appeal filed); *In re Bayer Phillips Colon Health Probiotic Sales Practices Litigation*, No. 11-03017, 2017 WL 139483, at *10-11 (D.N.J. Apr. 18, 2017). No court should further acknowledge or extend the misguided reasoning in *Mullins*.

In derogation of *King Bio* and its statutory underpinnings, *Mullins* failed to draw any meaningful distinction between lack of substantiation cases – cases properly brought by regulators – and cases by private plaintiffs, which must be based on affirmative evidence of falsity. By allowing a private plaintiff to allege a mere debate among experts, rather than actual falsity or deception, *Mullins* allows a private plaintiff to delve into the unique province of regulators. If *Mullins* is to be followed, the dietary supplement industry and its consumers alike will be adversely impacted.

III. THE PUBLIC INTEREST IS SERVED BY PROPERLY APPLYING *KING BIO*

A. *King Bio* Empowers Government Regulators Who Are Uniquely Positioned to Assess the Substantiation Underlying Health Benefit Claims

The evidence underlying health benefit claims for dietary supplements and other foods is often extremely complex, with studies utilizing a variety of different designs and sometimes yielding inconsistent results. Regulators, however, are uniquely equipped with the appropriate expertise to not only assess the science but also consider it in the context of the nature and cost of a product, the potential value of a the claimed benefits to consumers, and the potential costs of additional research.

In addition to state regulators, the Food and Drug Administration ("FDA") and Federal Trade Commission ("FTC") share jurisdiction over advertising claims for dietary supplements. *See* 15 U.S.C. §§ 45(a)(1), 52(a) (allowing FTC to take enforcement action against false and deceptive advertising practices in commerce); 21 U.S.C. § 331 (allowing FDA to take action against misbranded products in interstate commerce). Courts have long acknowledged FDA's technical and scientific expertise regarding the broad range of products regulated by the agency. *See, e.g.*, *Henley v. FDA*, 77 F.3d 616, 621 (2d Cir. 1996) ("FDA possesses the requisite know-how to conduct such [scientific] analyses, by sifting through the scientific evidence to determine the most accurate and up-to-date information"). Both legal and scientific experts at FDA have authority to review promotional claims for dietary supplements and to issue regulations that govern claims made in labeling and advertising. In addition, FDA offers a variety of guidance documents, for the food and supplement industries, explaining how it weighs various types of studies and under what circumstances it will consider evidence, such as *in vitro* or animal testing. *See, e.g.*, FDA, Guidance for Industry: Substantiation for Dietary Supplement Claims Made Under Section 403(r)(6) of the Federal Food, Drug, and Cosmetic Act (Dec. 2008); FDA, Guidance for Industry: Structure/Function Claims, Small Entity Compliance

Guide (Jan. 9, 2002); FDA, Guidance for Industry: Evidence-Based Review System for the Scientific Evaluation of Health Claims (Jan. 2009).

Likewise, the FTC brings expertise to the regulation of dietary supplement and food advertising. For decades, courts have credited the FTC's unique expertise in reviewing consumer advertising and have noted its important role in setting practice for advertisers. *See POM Wonderful, LLC v. FTC*, 777 F.3d 478, 490 (D.C. Cir. 2015) (quoting *FTC v. Colgate-Palmolive Co.*, 380 U.S. 374, 385 (1965)) ("The Commission 'is often in a better position than are courts to determine when a practice is deceptive within the meaning of the [FTC] Act,' and that 'admonition is especially true with respect to allegedly deceptive advertising since the finding of a § 5 violation in this field rests so heavily on inference and pragmatic judgment.'"). The FTC, like FDA, has also issued comprehensive guidance documents for the industry on its substantiation standards, which have been developed over the course of decades of investigations and litigation both in federal court and in its administrative court. *See, e.g.*, FTC, Policy Statement Regarding Advertising Substantiation (Mar. 11, 1983), appended to *Thompson Medical Co.*, 104 F.T.C. 648, 839 (1984), aff'd, 791 F.2d 189 (D.C. Cir. 1986), cert. denied, 479 U.S. 1086 (1987); FTC, Policy Statement on Deception (Oct. 14, 1983); FTC, Enforcement Policy Statement on Food Advertising (May 13, 1994); FTC, Dietary Supplements: An Advertising Guide for Industry (Apr. 2001).

The approval process for FDA's health claim for folic acid provides an informative example that illustrates the complexity of nutritional science and how regulators nevertheless routinely reach decisions with the public health considerations in mind. While most government assessments of claim substantiation occur the opportunity for public observation or participation, FDA's approval of "health

claims" (claims associating a substance and disease risk) utilizes notice and comment rulemaking.[2]

In determining whether to authorize a claim associating folic acid with a reduced risk of neural tube defects, FDA and other stakeholders carefully reviewed the science and public health implications. *See* 61 Fed. Reg. 8752 (Mar. 5, 1996). Only a small number of relevant studies existed: two randomized controlled studies, one of which was conducted in Hungary, and five observational studies. *Id.* at 8756. In order to assist in its assessment, FDA convened the Folic Acid Subcommittee and reviewed comments from "invited guest consultants; other Federal agencies; a foreign government; State departments of agriculture, consumer services, or health; health care professionals; consumers; consumer advocacy groups; national organizations of health care professionals; State and territorial public health nutrition directors; [and] manufacturers and suppliers of vitamins to the conventional food industry and the dietary supplement industry," among others. *Id.* at 8755.

FDA received a wide range of comments representing divergent views, and even its own convened panel did not reach consensus on authorizing the claim. "[M]embers of the Folic Acid Subcommittee who opposed a health claim cited the weakness of the data supporting the relationship, including the very small number, and observational nature, of studies relating intake of folate at levels attainable from usual diets to reduced risk of neural tube defects and the many issues associated with the interpretation of these studies." *Id.* at 8756. FDA itself acknowledged that "there are still significant gaps in our knowledge about the etiology of neural tube defects; about how folate, either alone or in combination with other nutrients, reduces the risk of neural tube defects; about dose-response relationships between folate intake and

[2] FDA has the authority to authorize "health claims" which are claims that associate a dietary substance with a reduction in disease risk. 21 U.S.C. § 343(r)(1)(b); 21 C.F.R. § 101.14(a)(1); *Whitaker v. Thompson*, 353 F.3d 947, 949 (D.C. Cir. 2004).

reduction in risk of neural tube defect-affected pregnancies; and about the role of other essential nutrients in the etiology of neural tube defects." *Id.*

Despite the divergent views on this issue, FDA ultimately authorized a claim. *Id.* at 8752; 21 C.F.R. § 101.79 (rule authorizing folic acid health claim). The agency determined that enough consistent evidence existed, and it stated that "it . . . expected that consumption of adequate folate will avert some, but not all, neural tube defects." *Id.* at 8780. The authorized folic acid health claim remains in place and provides a uniform standard that may be used in the labeling or advertising of any dietary supplement or food that meets the standard.

Given the complexities of nutrition science and the unique expertise – and public health mindset – of regulators, this discrete group of government officials should continue to be the sole arbiters in determining whether substantiation is adequate in a given case, thereby promoting not only truthful advertising, but more uniform outcomes. If private actors are allowed to seize on any inconsistency or weakness that might be found in a complex body of research, both advertisers – and consumers who rely on their products – stand to be harmed. Allowing a patchwork of conflicting private actor-driven decisions on any single dietary ingredient stands to dilute the significance and authority of expert government actors and discourage manufacturers from innovating in the nutrition space or disseminating health benefit claims at all.

King Bio properly limits the role of private litigants by requiring that they "affirmatively prove that [an advertising claim] is a false or misleading statement and not merely one that is unsubstantiated." *Scheuerman*, No. 10-3684 (FSH)(PS), 2012 WL 2916827, at *7.

B. *King Bio* Protects Advertisers from Undue Burdens

As recognized in *King Bio*, limiting the role of private actors in false advertising cases "prevents undue harassment of advertisers" and allows for "the least

burdensome method of obtaining substantiation for advertising claims." *King Bio*, 107 Cal. App. 4th at 1345.

Government investigations of advertising substantiation are expansive, with regulators seeking not only the underlying science supporting claims, but also all underlying data and documentation from studies, copies of all offline and online advertising, dissemination schedules for all advertising, and/or any and all communications relating or referring to advertising claims or substantiation. Responding to an investigation is also disruptive and requires extensive resources. In fact, in recognition of the significant burdens that companies face in its investigations, the FTC, recently launched an initiative to streamline its investigatory procedures. *See* FTC, Press Release, Process Reform Initiatives are Already Underway at the Federal Trade Commission: Acting Chairman Ohlhausen Is Streamlining Agency Processes and Improving Transparency (Apr. 17, 2017) ("New groups within the Bureau of Competition and the Bureau of Consumer Protection are working to streamline demands for information in investigations to eliminate unnecessary costs to companies and individuals who receive them.").

At the same time that government investigations require substantial time and resources, dietary supplement advertisers are being inundated with demands from plaintiff's firms. *King Bio* serves an important role in limiting the role of private actors and preserving the sole authority of government actors to review and assess claim substantiation. And by following *King Bio*, dietary supplement advertisers are also shielded from an unnecessary and burdensome source of litigation.

CONCLUSION

For the foregoing reasons, CRN urges this court to continue to follow the precedent set in *King Bio*.

DATED: Mav 15. 2017

KELLEY DRYE & WARREN LLP

By: */s/ David E. Fink*
David E. Fink

10100 Santa Monica Blvd., 23rd Floor
Los Angeles, California 90067
Telephone: (310) 712-6100
Facsimile: (310) 712-6199
dfink@kelleydrye.com
Attorneys for Amicus Curiae
The Council for Responsible Nutrition

CERTIFICATE OF SERVICE

I hereby certify that I electronically filed the foregoing with the Clerk of the Court using the CM/ECF system which will send notification of such filing to the Electronic Service List for this Case.

Dated: May 15, 2017

KELLEY DRYE & WARREN LLP

By: */s/ David E. Fink*
David E. Fink
Attorneys for Amicus Curiae
The Council for Responsible Nutrition